DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MicroPort Orthopedics, Incorporated
Mr. Matt Paul
Regulatory Affairs Project Manager
5677 Airline Road
Arlington, Tennessee 38002

April 10, 2015

Re: K150302
Trade/Device Name: PROFEMUR® Preserve Classic Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: February 5, 2015
Received: February 6, 2015

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150302 (page 1/1)

Device Name
PROFEMUR® Preserve Classic Stem

Indications for Use *(Describe)*
The PROFEMUR® Preserve Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Preserve Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Preserve Classic Stems.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 901-867-4350 Fax: 901-451-6018
Date:	February 5, 2015
Contact Person:	Matt Paul *Regulatory Affairs Project Manager*
Proprietary Name:	PROFEMUR® Preserve Classic Stem
Common Name:	Hip Stem
Classification Name and Reference:	888.3353 LZO Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis - Class II
Subject Product Code and Panel Code:	Orthopedics/87/ LZO
Predicate Device:	PROFEMUR® Preserve Stem (K112080)
Reference Devices:	DYNASTY® Biofoam Shell (K122382) PROFEMUR® TL Classic Hip Stem (K123688) PROFEMUR® TL Classic Long Neck Hip Stems (K140676)

I. Device Description

The PROFEMUR® Preserve Classic Stems are monolithic femoral components manufactured from a forged titanium alloy (ASTM F620). The hip stems are designed for use in cementless total hip arthroplasty and possess identical indications for use to the predicates (K112080). The design features of the PROFEMUR® Preserve Classic Stems are summarized below:

- Stems are forged from Ti6Al4V alloy conforming to ASTM F620
- Stems possess unalloyed titanium plasma coating manufactured from powder conforming to ASTM F1580
- Neck offsets are offered in Straight and Varus 8° options
- Stems are offered in twelve sizes for both neck offsets

II. Indications for Use

Identically to the predicate, the PROFEMUR® Preserve Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Preserve Classic Stems are single use components, intended for use in uncemented total hip arthroplasty.

PROFEMUR® Preserve Classic is intended for use with the sterile compatible components listed in **Table 1** below, identical to the predicate.

Table 1. Compatible Components	
510(k)	**Intended Combinations**
Modular Femoral Neck Sleeves	
K072656	Short to X-long neck sleeves to use with ceramic-polyethylene with ID 38-46mm
Modular Femoral Heads	
K953025	Metal-Polyethylene, OD 28mm XXL
K932222	Metal-Polyethylene, OD 28mm
K920593	Ceramic-Polyethylene, OD 28mm
K925512	Ceramic-Polyethylene, OD 28mm
K893685	Ceramic-Polyethylene with ID 28-36mm
K002149	Metal-Polyethylene with ID 22-36mm, OD 42-68mm
K051348	Metal-Polyethylene with ID 36-56mm
K072656	Ceramic-Polyethylene with ID 38-46mm
Acetabular Shell and Inserts	
K002149	Metal-Poly with ID 22-36mm, OD 42-68mm
K043073	Metal-Polyethylene and Ceramic-Polyethylene with ID 22-36mm, OD 46-68mm
K043099	Metal-Polyethylene and Ceramic-Polyethylene with ID 22-36mm, OD 46-68mm
K052026	Metal- Polyethylene and Ceramic-Polyethylene with ID 28-36mm
K061547	Metal- Polyethylene with ID 32-42mm, OD 50-58mm
K070785	Metal-Polyethylene and Ceramic-Polyethylene with ID 28-46mm, OD 46-68mm
K082924	Metal-Polyethylene with ID 28-54mm, OD 46-76mm
	Ceramic-Polyethylene with ID 50-54mm
K122382	Metal-Polyethylene with OD 46-76 mm

III. Nonclinical Testing

The subject PROFEMUR® Preserve Classic Stems were evaluated for range of motion in accordance with ISO 21535. The stems were also successfully evaluated by proximal fatigue testing according to ISO 7206-6. The subject stems were verified to be applicable to ISO 7206-4 distal fatigue testing that was performed on a modular stem possessing a similar geometry. The FEA models used in comparison were previously validated in testing submitted in K141235. Successful results of testing support the expectation that the device will perform as intended under normal physiological loading conditions, and support the substantial equivalence of the PROFEMUR® Preserve Classic Stem.

IV. Clinical Testing

Clinical data was not provided for the subject devices.

V. Technological Characteristics

The PROFEMUR® Preserve Classic Stems are designed to provide geometric sizing options that resemble a subset of those available with the predicate device. Furthermore, the subject devices are made from an identical titanium alloy (ASTM F620) and possess an identical titanium plasma spray coating design specification and material (ASTM F1580 powder) to the predicate device. Coating process and vendor information are identical to those provided for reference device K123688.

For all associated instruments that do contain colorants, detailed color additive information was provided for the same instruments in K140676.

VI. Substantial Equivalence Information

The intended use and indications for use of the PROFEMUR® Preserve Classic Stems are identical to those of the predicate devices (K112080). The materials of the subject devices are identical to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to that of the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification. For more details on subject and predicate comparison, see the comparison table located in the Device Description (**Tab 014**).

VII. Conclusion

The design features, subject and predicate testing, materials information, and analysis data provided in this premarket notification adequately support the substantial equivalence of the PROFEMUR® Preserve Classic Stem.